

3773. Adulteration and misbranding of adhesive bandages. U. S. v. 35 Boxes, etc. (and 1 other seizure action). (F. D. C. Nos. 32481, 32523. Sample Nos. 980-L, 981-L, 1266-L, 1267-L, 37768-L, 37769-L.)

LIBELS FILED: On or about February 7, 1952, Middle District of North Carolina and Eastern District of New York.

ALLEGED SHIPMENT: On or about December 17 and 28, 1951, by Medical Fabrics Co., Inc., from Paterson, N. J.

PRODUCT: 309 boxes each containing 100 *adhesive bandages*, and 182 boxes each containing 50 *adhesive bandages*, at Lexington, N. C., and Brooklyn, N. Y.

LABEL, IN PART: "2" x 2¾" 'Presso' Patch [or "Round Presso Patch"] Sterilized Plain Pad Elastic Adhesive Occlusive Dressing," "3" x 3" 4-Wing 'Presso' Joint Patch Elastic Adhesive Dressing * * * Sterilized," and "1" x 3" 'Presso-plast' Elastic Stick Pad * * * Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive Absorbent Bandage," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since the article was not sterile.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading as applied to the article, which was not sterile but was contaminated with living micro-organisms.

DISPOSITION: April 30, 1952. Medical Fabrics Co., Inc., having appeared as claimant and the libel proceedings having been consolidated for hearing before the United States District Court for the Eastern District of New York, and the claimant having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for reprocessing, under the supervision of the Federal Security Agency.

3774. Adulteration of hypodermic syringes. U. S. v. 132 Syringes, etc. (F. D. C. No. 32366. Sample No. 10817-L.)

LABEL FILED: December 20, 1951, Southern District of Indiana.

ALLEGED SHIPMENT: On or about November 9, 1951, by E. Miltenberg, Inc., from New York, N. Y.

PRODUCT: 132 2-cc. size, 9 5-cc. size, and 9 10-cc. size *hypodermic syringes* at Indianapolis, Ind. Examination showed that approximately 25 percent of the syringes were defective in that the metal tip at the bottom of the syringe was cracked, thereby permitting a substantial portion of the medication to escape through the crack when one attempted to inject the medication by pressing on the plunger.

LABEL, IN PART: "Miltex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported to possess since its quality was impaired by a crack in the metal tip, permitting leakage of the medication to be injected by use of the article.

DISPOSITION: July 28, 1952. Default decree of forfeiture. The court ordered that a portion of the article, namely, 63 of the syringes which were found to be

not defective, be delivered to a State agency, and that the remainder of the article be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS *

3775. Misbranding of Gramer's Sulgly-Minol. U. S. v. 213 Bottles, etc. (and 1 other seizure action). Judgment for claimant; reversed on appeal. Decree of condemnation and destruction. (F. D. C. Nos. 28497, 28679. Sample Nos. 50094-K, 50095-K, 68846-K.)

LIBELS FILED: January 3 and 10, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about October 15 and 17 and November 22, 1949, by Walter W. Gramer, from Minneapolis, Minn.

PRODUCT: 366 4-ounce bottles of *Gramer's Sulgly-Minol* at Seattle and Mount Vernon, Wash., together with a number of leaflets entitled "Arthritis Hundreds Claim Its Grip Broken" and "A Light Should Not Be Hidden." Examination disclosed that the product consisted essentially of a lime and sulfur solution.

LABEL, IN PART: "Gramer's Sulgly-Minol A Solution of Sulphur, Glycerine, Sulphurated Lime and Isopropyl Alcohol 6%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was effective as a treatment, cure, and preventive for rheumatism and arthritic conditions and as a treatment for boils and acne. The article was not effective for such purposes.

DISPOSITION: Walter W. Gramer, claimant, filed answers to the libels on May 16, 1950, denying that the product was misbranded and affirmatively alleging that the issues raised by the libels had been adjudicated previously in his favor in a criminal case filed by the Government against him in the District of Minnesota. On May 22, 1950, an order was entered consolidating the two libel actions. Thereafter, a motion to strike the affirmative defense from the defendant's answers was filed by the Government, and on August 22, 1950, this motion was denied. Following this denial, a motion for summary judgment was made by the claimant on the ground that there was no genuine issue as to any material fact and that claimant was entitled to a judgment as a matter of law.

On September 11, 1950, the court granted the claimant's motion for summary judgment. An appeal was taken by the Government to the United States Court of Appeals for the Ninth Circuit, and on September 28, 1951, the following opinion was handed down by that court:

STEPHENS, *Circuit Judge*: "A criminal action brought by the United States against Walter W. Gramer in a federal district court in Minnesota in 1949 charged Gramer, claimant herein, with the introduction into interstate commerce of misbranded drugs in violation of the Federal Food, Drug, and Cosmetic Act.¹ After a plea of not guilty was entered, a trial on the merits was had and the district judge, sitting without a jury, adjudged claimant not guilty.

*See also Nos. 3768-3773.

¹ Title 21, U. S. C. A. § 301, et seq.